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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,254	07/14/2003	Steven W. Dow	2880	9736

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/621,254	DOW ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/12/1006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,31-121 and 143-150* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23,31-121 and 143-150* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The response to the restriction requirement mailed 9/13/2006 is acknowledged. However, upon further consideration, a new restriction is set forth. Applicants pointed to errors in the previous restriction requirement, where not all of the claims were classified into invention groups. Also, upon further consideration, the invention groups have been altered.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 44-46, 52-53, 98, 99, 102, 103 drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a portion of a bacterium.

II. Claims 47-49, 54, 55, 108 and 109, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a portion of a fungal organism.

III. Claim 50, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a portion of a multicellular organism.

IV. Claim 51, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises portion of a unicellular organism.

V. Claims 56, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises molecules from a viral organism.

VI. Claims 57, drawn to compositions comprising a ligand for pattern recognition family of receptors, which ligand comprises molecules derived from a rickettsial organism.

VII. Claims 58, drawn to a composition comprising a ligand for pattern recognition family of receptors, which ligand comprises molecules derived from a parasitic organism.

VIII. Claim 59, drawn to a composition comprising a ligand for pattern recognition family of receptors, which ligand comprises molecules derived from an arthropod organism.

IX. Claims 60-62, 67, 68, 104-107, drawn to a composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a nucleic acid or a nucleic acid encoding a TLR ligand.

X. Claims 9, 10, 86, 87, 112-121, drawn to methods of treating cancer comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.

XI. Claims 11, 12, 88, 89, drawn to methods of treating infections disease, comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.

XII. Claims 13-15, drawn to methods of treating allergic disease comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.

XIII. Claims 16-22, drawn to methods of treating autoimmune disease comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.

XIV. Claims 143-145, drawn to methods of bone healing comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.

XV. Claims 146-150, drawn to methods of relieving injury comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.

3. Claims 1-8, 23 and 83-85 link inventions X-XV. Claims 31-43, 63-66, 69-82, 90-97, 100, 101, 110 and 111 link inventions I-IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-8, 23 and 83-85 or claims 31-43, 63-66, 69-82, 90-97, 100, 101, 110 and 111. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims in the instant application. Where a restriction requirement is withdrawn, the provisions of

35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other, for of the following reasons:

Each of inventions I-IX is drawn to a composition comprising a separate and distinct product. In the case of group I, the product is a portion of a bacterium. In the case of group II, the product is a portion of a fungal organism. In the case of group III, the production is a protion of a multicellular organism. In the case of group IV, the product is a portion of a unicellular organism. In the case of group V, the product is a molecule derived from a viral organism. In the case of group VI, the product is a molecule derived from a rickettsial organism. In the case of group VII, the product is a molecule derived from a parasitic organism. In the case of group VIII, the product is a molecule derived from an arthropod. In the case of group IX, the product is a nucleic acid or nucleic acid encoding a TLR ligand. Each of these products encompasses a separate and distinct genus of products that would require a separate search in the non-patent literature. Furthermore, the search in the patent and non-patent literature would not be limited to the products in the context of the intended use of the products or by the function of binding to a particular receptor. Applicants have argued in previous responses that it is incorrect to restrict a generic invention. In response it is noted that the linking claims will be examined along with the elected group so that any issues pertaining to the generic concept of the invention will be examined, and that if generic claims are found allowable the restriction requirement between the different groups of products will be removed.

Because the genus of ligands to pattern recognition molecule family of receptors clearly encompasses a wide range of varying molecules and compositions, it would impose an undue burden on the examiner to have to search and examine any of inventions I-IX together, because the search for each of the invention groups would not be coextensive and involves search of generic classes of products.

Inventions X and any of XI, XII, XIII, XIV and XV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct because each of the inventions is directed to the treatment of a separate class of disease. In the case of invention X, the class of disease is cancer, which is a separate and distinct class of disease from infectious diseases; or from allergic diseases; or from autoimmune diseases; or from diseases of bone; or from injury. Treatment for each of these diseases encompasses methods that have a different effect. In the treatment of cancer the endpoint may be inhibition of tumor growth or eradication of a tumor; in treatment of infectious disease the endpoint is to rid the host of the infectious agent; in the treatment of allergic diseases the endpoint is to alter the response of the immune system to external antigens; in the treatment of autoimmune disease the endpoint is to alter a malfunctioning of the immune system in distinguishing self from non-self; in the treatment of diseases of the bone, the endpoint is to affect bone growth or response to a bone graft; and in the treatment of injury the endpoint is to alleviate symptoms associated with oxidative injury or apoptotic injury that may occur in

response to a primary mode of treatment. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Therefore, it would impose an undue burden on the examiner to have to search and examiner any of inventions X-XV together, because the search for each of the invention groups would not be coextensive and involves searches of separate and distinct classes of disease processes.

Inventions I-IX, and X-XV are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the compositions of any of inventions I-IX appear to be useful for generally stimulating an immune response to a specific antigen in addition to having use in methods of treatment of diseases of inventions X-XV. Additionally, the processes of treatment of diseases such as cancer, infectious disease, allergy, autoimmune disease, bone healing or treatment of injury may be practiced with another materially different product from the products of any of inventions. Thirdly, each of the diseases of invention groups X-XV represents a separate and distinct process of using the claimed products of invention groups I-IX.

Furthermore, it would impose an undue burden on the examiner to have to search and examiner any of inventions X-XV together with any of inventions I-IX, because the search for each of the invention groups would not be coextensive and involve a search for the products that is not limited by the intended use of the claimed products.

Species Election:

If any of inventions I-IX is elected then an election of species is required.

This application contains claims directed to the following patentably distinct species:

I. species of molecule:

a) glycoprotein

b) lipoprotein

c) glycolipid

d) carbohydrate

e) lipid

f) nucleic acid

g) protein or peptide sequence

The species are independent or distinct because they are drawn to independent and distinct classes of molecules. If species "f" is elected, then claims directed to group IX will be examined.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 31-43, 63-66, 69-82, 90-97, 100, 101, 110 and 111 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If any of inventions I-IX is elected then a further election of species is required.

This application contains claims directed to the following patentably distinct species:

II. species of antigen:

a) intact microorganism

b) protein or peptide molecule

c) carbohydrate molecule

d) lipoprotein molecule

e) glycopeptide or glycoprotein molecule

f) glycolipid molecule

g) lipid molecule

h) cell

The species are independent or distinct because they are drawn to independent and distinct classes of molecules, and to microorganisms and cells.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 31-43, 63-66, 69-82, 90-97, 100, 101, 110 and 111 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If any of inventions X-XV is elected then an election of species is required.

This application contains claims directed to the following patentably distinct species:

III. species of ligand:

a) glycoprotein

b) lipoprotein

c) glycolipid

d) carbohydrate

e) lipid

f) nucleic acid

g) protein or peptide sequence

h) portion of a bacterium

i) portion of fungus

j) portion of a multicellular organism

k) portion of a unicellular organism

The species are independent or distinct because they are drawn to independent and distinct classes of molecule or organism.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-23, 83-89, 112-121 and 143-150 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In re Ochiai:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn

process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
December 26, 2006

CHRISTOPHER H. YAEN
PRIMARY EXAMINER